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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/802,726	03/18/2004	Daniele Galavotti	27420/GM/CB	5027

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Via Meravigli, 16
MILANO, 20123
ITALY

EXAMINER

BEISNER, WILLIAM H

ART UNIT	PAPER NUMBER
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1744

MAIL DATE	DELIVERY MODE
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06/22/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/802,726

Applicant(s)

GALAVOTTI, DANIELE

Examiner

William H. Beisner

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-32 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-32 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 18 March 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☒ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|----------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>9/15/04</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Priority

1. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Information Disclosure Statement

2. The information disclosure statement filed 9/15/2004 has been considered and made of record.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1-18 and 26-32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

With respect to claim 1, while the claim recites that the device includes a first and second bundle of hollow fibers and the locations of the bundles, the claim is devoid of any language that clearly indicates the fluid communication of the open ends of the hollow fibers in the bundles. In the absence of such language, the metes and bounds of the claim cannot be clearly determined.

Claims 2-18 and 26-32 are indefinite based on their dependency from indefinite claim 1.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1-5, 9-19, 21 and 23-32 are rejected under 35 U.S.C. 102(b) as being anticipated by Galavotti (WO 02/18535).

With respect to claim 1, the reference of Galavotti discloses a bioreactor (1), particularly for bioartificial organs, comprising a closed and substantially tubular body (2) inside which there is a containment cavity (3); an animal and/or human cell culture and support structure (4), accommodated in said cavity and suitable to be crossed by a fluid to be processed; a port (5) for the inflow of said fluid to be processed, which is formed in said body upstream of said structure; a port (6) for the outflow of the processed fluid, which is formed in said body downstream of said structure; a first chamber (7) for collecting the fluid to be processed, which is formed in said cavity upstream of said structure and is connected to the outside of said body by means of said inflow port (5); and a second chamber (8) for collecting the processed fluid, which is formed in said cavity downstream of said structure and is connected to the outside of said body by means of said outflow port (6); comprising a first bundle (16) of hollow capillary fibers (17) for the inflow of said fluid to be processed, which is accommodated in said cavity (3) and interposed between said first collection chamber (7) and said structure (4), and a second bundle (21) of hollow capillary fibers (22) for the outflow of said processed fluid, which is accommodated in said cavity (3) and is interposed between said structure (4) and said second collection chamber

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(8). Note while the fiber bundles extend into the structure (4), in the absence of further positively recited structure, the fiber bundles of Galavotti are also “interposed” between the collection chambers (7, 8) and structure (4).

With respect to claim 2, the bioreactor (1) includes first anchoring means (24) and second anchoring means (24) for said first bundle (16) and said second bundle (21) of fibers respectively.

With respect to claim 3, the bioreactor body (2) comprises two opposite ends closed hermetically by respective covers (10, 11), said inflow port (5) being formed in one of said covers, said outflow port (6) being formed in the other one of said covers.

With respect to claim 4, the bioreactor (1), includes at least one inlet (12, 9) for the inoculation of said cells, which is formed in said body between said first bundle and said second bundle of fibers.

With respect to claim 5, the bioreactor (1) includes at least one outlet port (13) for the evacuation of the inoculated cells that have not adhered to said structure formed in said body between said first bundle and said second bundle of fibers.

With respect to claim 9, the bioreactor (1) includes plugs for closing said inoculation inlet (12) and said evacuation outlet (13) (See page 8, lines 20-21).

With respect to claim 10, the bioreactor (1) includes a panel (14) that is wound on itself in a roll or spiral with an axis that is substantially parallel to the longitudinal axis of said body, the longitudinal edge of said panel arranged inside said roll or spiral being free, the opposite longitudinal end being free and in contact with the inside wall of said cavity.

With respect to claim 11, the said panel (14) is wound around said internal longitudinal edge through an arc of at least 270° (See claim 8).

With respect to claim 12, said panel (14) comprises at least two mutually superimposed and parallel plate-like layers, a first layer (18) comprising a matrix for supporting said cells, a second layer (19) comprising a matrix for diffusing and distributing the inoculated cells.

With respect to claim 13, said panel (14) comprises a third layer (20) that is identical to said first layer and is superimposed on said second layer and parallel thereto.

With respect to claim 14, said first layer (18) and/or said third layer (19) are permeable with respect to said fluid (See page 5, lines 19-30).

With respect to claim 15, said first layer (18) and/or said third layer (20) are constituted by sheets of polymeric fabric having a crossed weave with a random or ordered arrangement (See page 6, lines 5-7).

With respect to claim 16, said polymeric fabric of said first layer and/or of said third layer is made of polyester or the like (See page 6, lines 5-7).

With respect to claim 17, the total volume of said first layer and/or said third layer is comprised between 5 and 15% of the total volume available for said cells (See claim 12).

With respect to claim 18, said second layer (19) has a lattice-like structure (See Figure 4).

With respect to claim 19, said first bundle (16) of fibers (17) comprises at least one flat order of hollow capillary fibers that are arranged substantially parallel to the longitudinal axis of said body and are individually bent in a U-shape, with their respective open ends directed toward said first collection chamber (7), said fibers being permeable to said fluid (See page 5, line 19, to page 6, line 4).

With respect to claim 21, said second bundle (21) of fibers (22) comprises at least one flat order of hollow capillary fibers that are arranged substantially parallel to the longitudinal axis of said body and are individually folded in a U-shape, their respective open ends being directed toward said second collection chamber (8), said fibers being permeable to said fluid (See page 5, line 19, to page 6, line 4).

With respect to claim 23, each one of said fibers of said first bundle and of said second bundle is constituted by a segment of a capillary tube made of microporous material which is bent in a U-shape substantially at the centerline so as to form two straight branches which are mutually substantially parallel and have open ends that lead respectively into said first collection chamber and into said second collection chamber (See page 5, line 19, to page 6, line 4, and page 6, lines 17-25).

With respect to claim 24, said microporous material has pores with an average diameter comprised between 0.10 μm and 0.50 μm (See page 6, lines 17-25).

With respect to claim 25, said microporous material is constituted by polyether sulfone or the like (See page 6, lines 17-25).

With respect to claim 26, the distribution density and the diameter of said fibers are constant throughout the extension of said first bundle and/or said second bundle (See page 5, line 19, to page 6, line 4, and page 6, lines 17-25).

With respect to claim 27, said first anchoring means (24) and said second anchoring means (24) comprise at least-one layer of sealing material that is accommodated snugly in said cavity, is arranged substantially at right angles to the longitudinal axis of said body, and in which

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the fibers of said first bundle and of said second bundle respectively are embedded at least partially (See page 6, lines 8-11).

With respect to claim 28, said sealing material is of the polymeric type based on polyurethane or the like (See page 6, lines 8-11).

With respect to claim 29, said first collection chamber (7) and said second collection chamber (8) are formed respectively between said covers (10 and 11) and said first and second anchoring means (24).

With respect to claim 30, the direction of the flow of said inoculated cells from said inoculation inlet through said structure has a component that is substantially perpendicular and a component that is substantially parallel to the longitudinal axis of said body.

With respect to claim 31, the direction of the flow of said fluid from said inflow port to said outflow port through said structure is substantially parallel to the longitudinal axis of said body.

With respect to claim 32, said fluid can be plasma or ultrafiltrate.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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8. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. Claims 20 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Galavotti (WO 02/18535).

The reference of Galavotti has been discussed above.

Claims 20 and 22 differ by reciting that the first and second bundles of hollow fibers are positioned at an angle between 15 and 30 degrees with respect to one another.

In the absence of a showing of criticality and/or unexpected results, it would have been obvious to one of ordinary skill in the art at the time the invention was made to optimize the position of the bundles within the device while maintaining the required of flow of fluid within the device.

Allowable Subject Matter

10. Claims 6-8 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

11. The following is a statement of reasons for the indication of allowable subject matter:

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With respect to claims 6-8, while the closest prior art of Galavotti (WO 02/18535) discloses an inflow chamber (9a) for the inflow of cells, the prior art of record fails to teach or fairly suggest providing the device including the combination of elements of claim 6 with a chamber positioned between structure (4) and one of said bundles (16 or 21) of hollow fibers.

Conclusion

12. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

The reference of Gerlach (US 5,516,691) is cited as prior art that discloses the use of U-shaped hollow fibers within a bioreactor device (See Figures 6 and 8).

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to William H. Beisner whose telephone number is 571-272-1269. The examiner can normally be reached on Tues. to Fri. and alt. Mon. from 6:15am to 3:45pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gladys J. Corcoran can be reached on 571-272-1214. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



William H. Beisner
Primary Examiner
Art Unit 1744

WHB